REMARKS

Claims 51-68 are pending. Claims 51 and 55 were amended; the amendment is supported by disclosure on page 6, line 25-29, of the specification. New claims 61-68 are supported by disclosure on page 7, lines 3-6, and on page 23, lines 26-29, of the specification.

No new matter has been added to this application.

35 U.S.C. Section 102

Claim 51 was rejected for anticipation by Paul '989. The '989 patent describes *Lactobaccillus* sp. And *Bifidobacillus* sp. The passages to which the Examiner refers (Formulation J, col. 15, lines 18-19) describes a *Bifidobacterium adolescentis*. Claim 51 has been amended to require a *Bacillus coagulans* bacterium. The '989 patent fails to describe *Bacillus coagulans*; therefore, this claim is not anticipated by the cited reference.

Claim 57 was rejected for anticipation by Reid '551. The "Reid '551 reference appears not be of record in this case, not having been cited in the IDS filed on November 17, 1999; the Office Action mailed on March 29, 2000; the Supplemental IDS filed on June 9, 2000, the Office Action mailed on December 26, 2000, nor the present Office Action. Neither a full citation nor copy of this reference was not provided; therefore, Applicant cannot properly respond to this rejection. However, upon searching the USPTO database, Applicant identified a patent (USPN 6,004,551) that may be the reference to which the Examiner refers. If so, the amendment to claim 57 (requiring *B. coagulans*) overcomes the rejection, because the USPN 6,004,551 fails to describe *B. coagulans*.

Claim 60 was rejected for anticipation by Langrehr. Claim 60 has been canceled by the present amendment. Therefore, this rejection is moot.

In view of the present amendment, Applicant submits that the rejections under §102 should be withdrawn.

35 U.S.C. section 103

Claims 51-60 were rejected for obviousness over Hata in view of Paul and Hansen, in further view of Long. At page 5, lines 8-13, of the present Office Action (Paper No. 13), the Examiner states:

> it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the composition and process of administering nutrients and (sic) disclosed by Hata by supplementing the milk containing composition yogurt, for example, with citrate or gluconate compounds as taught by Paul and Hansen for the expected benefit of increasing the digestibility and nutritional content of food and thus maximize the health benefits of the mammal being fed.

The claims have now been amended to require that the composition contain *B. coagulans*. The Examiner concedes that Hata do not describe a composition containing a fructo-oligosaccharide and gluconate or citrate. In fact, the Hata reference is limited to a description of a particular mutant of *B.coagulans* termed "EC-1", which has very specific growth requirements. In the paragraph spanning columns 4 and 5 of the Hata reference, the reference states: "Many well known sporiferous lactic acid bacteria can grow solely on yeast extracts, inorganic salts or sugars or additionally with peptone and meat extracts. However, the EC-1 bacterium according to the present invention cannot grow on even aggregates of these substances, but can only grow when it is cultured on a liquid or solid medium mainly composed of lactocasein and provided with fatty acid contained in protein and animal milk." (emphasis added) Thus, Hata describes very precise compositions in which this particular strain of *B. coagulans* will grow; Hata fails to

describe a fructo-oligosaccharide and gluconate or citrate and fails to suggest modifying the culture medium components from the precisely defined components described.

The secondary reference, Paul describes compositions containing lactic acid bacteria and fructo-oligosaccharides, but fails to describe *B. coagulans*. As is discussed above, Paul describes describe two types of bacteria: *Lactobaccillus* sp. and *Bifidobacillus* sp. These bacteria differ considerably from *B. coagulans*; therefore, one of skill in the art would not be motivated to combine these teachings or to modify the growth medium of Hata's bacteria with compounds used in growth media for *Lactobaccillus* sp. and *Bifidobacillus* sp., particularly in view of Hata's discussion on the unique growth requirements of *B. coagulans* EC-1.

The third reference, Hansen, describes making calcium–fortified yogurt using calcium gluconate and/or calcium citrate. Hansen also describes only *Streptococcus thermophilus* and *Lactobacilli burglarious* for yogurt culture. There is no suggestion to add calcium citrate or gluconate to any other bacterial cultures, much less *B. coagulans*.

Moreover, Hata describes a mixture of bacterial species, i.e., a yogurt composition into which *Bacillus coagulans* EC-1 has been introduced before or after the milk composition has been heated to a high temperature (about 100 degrees Celsius). Hata states that other bacteria (other *Bacillus* sp. and *Clostridium* sp.) are present, but at a reduced concentration because of the heat treatment. Thus, Hata administers a mixture of bacteria, rather than an isolated *Bacillus coagulans* as required by the amended claims.

Long describes adding lactase to lactose-containing compositions such as yogurt; however, this reference fails to suggest (and the cited combination of references) fails to suggest combining lactase with an isolated *B. coagulans*.

In view of the present amendment, Applicants request withdrawal of the rejections under §103.

35 U.S.C. § 112

Claims 51-55 and 58-59 were rejected for new matter and for indefiniteness. With regard to new matter, Applicant submits that support for mineral gluconate or citrate, i.e., a mineral in the gluconate or citrate form, appears at page 7, line 12, of the specification.

With regard to indefiniteness, Applicant submits that such compounds are well known forms of mineral formulations. Minerals in the form of a gluconate or citrate is described on page 7, line 12, and various examples of such compounds (e.g., potassium gluconate, calcium citrate, etc.) are given in Formulations 1-3 on page 25 of the specification. Moreover, the art to which the Examiner refers on page 4 of the Office Action (e.g., Hansen et al.) also make use of this standard nomenclature for mineral salts.

Accordingly, Applicant requests withdrawal of the rejections under § 112.

CONCLUSION

On the basis of the foregoing amendments, Applicant respectfully submits that the pending claims are in condition for allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact either of the undersigned at the telephone number provided below.

A petition for extension of time and a check in the amount of $460.00 is enclosed to cover the petition fee for a three month extension of time pursuant to 37 C.F.R. § 1.17(a)(3). Also filed herewith is a Request for Continued Examination with the required fee. The Commissioner is hereby authorized to charge any additional fees that may be due, or credit any

overpayment of same, to Deposit Account No. 50-0311, Reference No. 19374-504.

Respectfully submitted,

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Appendix: Marked up version of claim amendments

Cancel claim 60.

Amend claims 51 and 55.

51. (amended) A method of increasing bioavailability of nutrients in a mammal comprising buccally administering to said mammal a composition [comprising a lactic-acid producing bacteria] an isolated *Bacillus coagulans* bacterium, a fructo-oligosaccharide, and a mineral gluconate.

55. (amended) A method of increasing bioavailability of nutrients in a mammal comprising buccally administering to said mammal a composition comprising [a lactic-acid producing bacteria] an isolated *Bacillus coagulans* bacterium, a fructo-oligosaccharide, and a mineral citrate.

Add new claims 61-63.

61. The method of claim 51, wherein said bacterium is in the form of a dried cell mass.

62. The method of claim 51, wherein said bacterium is in the form of a stabilized gel or paste, or a stabilized liquid suspension.

63. The method of claim 55, wherein said bacterium is in the form of a dried cell mass.

64. The method of claim 55, wherein said bacterium is in the form of a stabilized gel or paste, or a stabilized liquid suspension.

65. The method of claim 57, wherein said bacterium is in the form of a dried cell mass.

66. The method of claim 57, wherein said bacterium is in the form of a stabilized gel or paste, or a stabilized liquid suspension.

67. The method of claim 51, wherein said composition is a gel, suspension, aerosol spray, capsule, tablet, wafer, powder, or semi-solid formulation.

68. The method of claim 55, wherein said composition is a gel, suspension, aerosol spray, capsule, tablet, wafer, powder, or semi-solid formulation.